December 1, 2021

Cathy Cook, MD
Medical Director
Capitol Bridge, LLC
National Correct Coding Initiative Contractor
P.O. Box 368
Pittsboro, IN 46167

Delivered Electronically via NCCIPTPMUE@cms.hhs.gov

Re: Procedure-to-Procedure (PTP) Edits Between Healthcare Common Procedure Coding System (HCPCS) codes 75574 and 0623T-0626T[0]

Dear Dr. Cook,

The American College of Radiology, American College of Cardiology, American Roentgen Ray Society, American Society of Neuroradiology, Association of University Radiologists, Radiology Society of North America, Society of Cardiovascular Computed Tomography, and the Society of Interventional Radiology strongly urge the removal of the National Correct Coding Initiative (NCCI) Procedure to Procedure (PTP) edits between HCPCS codes 75574 (Coronary Computed Tomography Angiography-CCTA) and 0623T, 0624T, 0625T and 0626T[0] (**A**therosclerosis **I**maging **Q**uantitative **C**omputed **T**omography [AI-QCT]). The rationale for the edits given in the current PTP files are that these are, "mutually exclusive procedures," but the service provided by 0623T-0626T is separate and distinct from the service of 75574.

The American Medical Association (AMA) Current Procedural Terminology (CPT®) Editorial Panel determined that the services provided by 0623T-0626T are not included in the service described by 75574, and that the services described by 0623T-0626T are not a fragmentation of the previously described 75574. The description of procedure for 75574 does not include the services of 0623T-0626T, because the Category III codes describe a service that was not conceived, nor possible or available, when 75574 was developed, described and valued. CPT edited the introductory language for 75574 in 2021 and added new introductory language for codes 0623T-0626T for 2022 to make it clear that services such as AI-QCT (codes 0623T-0626T) are not part of the base service described by 75574.

The introductory language to 0623T-0626T in the CPT 2022 Professional Edition and a recent October 2021 CPT Assistant article state:

"The coronary CTA is performed and interpreted as a separate service and is not included in the service of automated analysis of coronary CTA."[1]
"These new Category III codes represent unique services not previously described in the CPT code set."[2]

In addition, the introductory language for CCTA code 75574 states:

"Cardiac CT and coronary computed tomographic angiography include the axial source images of the pre-contrast, arterial phase sequence, and venous phase sequence (if performed), as well as the two-dimensional and three-dimensional reformatted images resulting from the study, including cine review. Each of the contrast enhanced cardiac CT and coronary CTA codes (75572, 75573, 75574) <u>includes conventional quantitative assessment(s) intrinsic to the service listed in the code descriptor</u> (ie, quantification of coronary percentage stenosis, ventricular volume[s}, ejection fraction[s], and stroke volume[s], when performed."[1]

The new codes were granted because there is now the ability to evaluate the CCTA data **beyond** <u>the conventional quantitative assessment(s) intrinsic to the service listed in the code descriptor for 75574</u>. The diagnostic information that can be derived from AI-QCT enhances patient care with different information that cannot be attained in a clinical setting without sophisticated and trained software to perform the analysis. Further, the software is not available on existing CT scanners or interpretation platforms, nor is it available for physicians to perform as part of their standard interpretation of CCTA data.

There is precedent in the NCCI process for this type of service. For example, codes 0501T-0504T describe a service (FFR$_{CT}$) that utilizes CCTA data to produce clinical information not included in code 75574, and there are no PTP edits for these services with 75574, as it is reporting diagnostic information different than that reported by CCTA. The AI-QCT service (0623T-0626T) is significantly different from FFR$_{CT}$, providing completely different clinical information. However, the AI-QCT service is similar in that both services utilize CCTA datasets, both use FDA-approved algorithms, and both services provide additional (but significantly different) diagnostic information that is not included in 75574. We believe that AI-QCT should be recognized by NCCI as a separate service from CCTA, and that (like FFR$_{CT}$) there should be no PTP edits that preclude reporting AI-QCT with 75574.
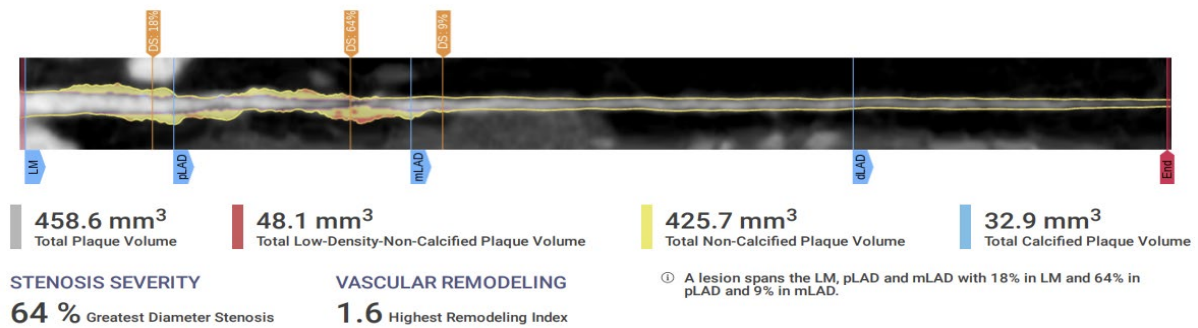
The additional clinical information gained through AI-QCT provides new information that is not evaluated or reported with the service described by 75574 and improves diagnostic accuracy. The current FDA-cleared software (Cleerly Labs; Cleerly, Inc.) enables rapid analysis, making the service available in a clinical setting for the first time.[3,4] This valuable diagnostic information cannot be accessed without this additional analysis service over and above the conventional CCTA service.

The AI-QCT analysis produces an exacting quantification and characterization of atherosclerotic plaque and vascular morphology within the patient's coronary arteries. This analysis enables highly accurate diagnostic information used to answer clinical questions on cardiac event risk and necessity of the need for invasive coronary angiography (ICA). Provider and patient access to this additional information is critical to improved patient outcomes and better utilization of healthcare resources. These edits will significantly reduce Medicare beneficiary and other patient access to this new and differentiated technology that is poised to improve the diagnosis of coronary artery disease (CAD) and subsequent treatment decisions.

Codes 0623T-0626T represent a service where the previously acquired and interpreted CCTA image data is sent to a cloud-based service to be analyzed by both an automated software and trained CT technologists who ensure precision and accuracy. The interpreting clinician may then access a web-based platform to obtain the outputs and visualizations from the analysis, and review, revise, interpret, and report the findings. The images below show the visual and quantitative data that can only be derived from the AI-QCT service:
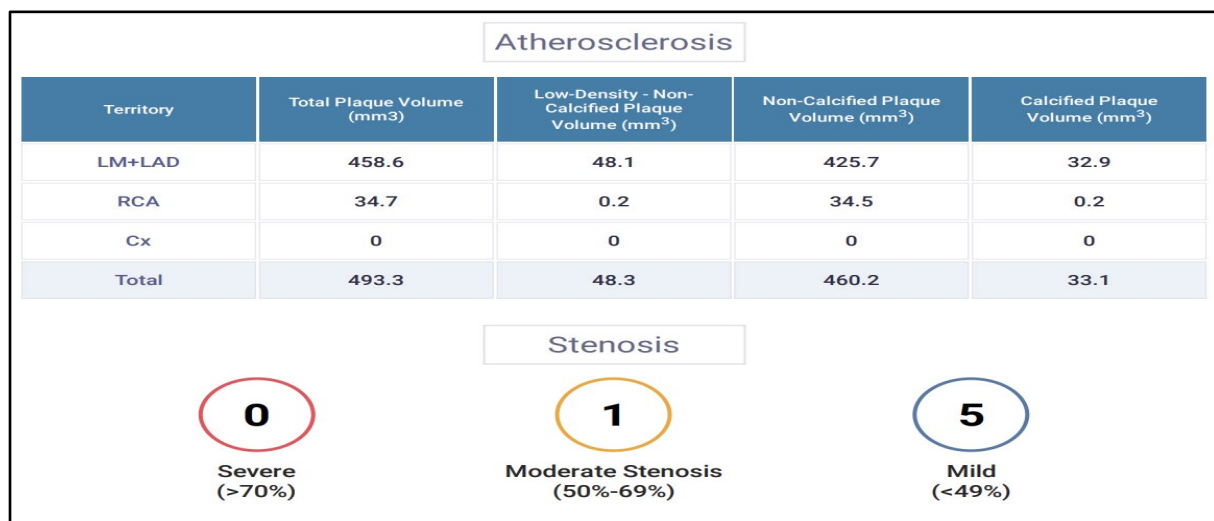
Figure 1.

Left Main and Left Anterior Descending (LM+LAD)

458.6 mm³	48.1 mm³	425.7 mm³	32.9 mm³
Total Plaque Volume	Total Low-Density-Non-Calcified Plaque Volume	Total Non-Calcified Plaque Volume	Total Calcified Plaque Volume

STENOSIS SEVERITY   VASCULAR REMODELING   ⓘ A lesion spans the LM, pLAD and mLAD with 18% in LM and 64% in pLAD and 9% in mLAD.

64 % Greatest Diameter Stenosis   **1.6** Highest Remodeling Index

The report from Cleerly Labs (Cleerly, Inc.) service shows segmentation of the Left Main and Left Anterior Descending Coronary Artery (LM+LAD) with precise stenosis determinations, color overlays of plaque deposits by type, and areas of positive vascular remodeling. The quantitative data shows plaque volumes in total and by type (in mm3), greatest stenosis diameter, and the vascular remodeling index.

Figure 2.

Atherosclerosis

Territory	Total Plaque Volume (mm3)	Low-Density - Non-Calcified Plaque Volume (mm³)	Non-Calcified Plaque Volume (mm³)	Calcified Plaque Volume (mm³)
LM+LAD	458.6	48.1	425.7	32.9
RCA	34.7	0.2	34.5	0.2
Cx	0	0	0	0
Total	493.3	48.3	460.2	33.1

Stenosis

0	**1**	**5**
Severe (>70%)	Moderate Stenosis (50%-69%)	Mild (<49%)

2

The report from Cleerly Labs (Cleerly, Inc.) shows quantitative analysis of plaque volumes in total and by type (in mm3) for each coronary artery where atherosclerosis was identified and the number of stenoses by severity index.

In a symptomatic patient with chest pain, the clinical utility of understanding plaque composition and volume include:

1. Improved detection (above certified Level III CCTA readers) of non-calcified and low-density plaques (highest risk of causing acute cardiac events)[5];
2. A new ability to understand an individual's response to medical therapy; to be able to determine if their plaque is progressing, regressing, or stabilizing with their current medical therapy[6-7];
3. Improved risk stratification for more precise medical management[8-10]; and,
4. Understanding the length and composition of each individual stenotic plaque to better plan an intervention and determine post intervention risk[11], if needed.

Obtaining the information from the AI-QCT analysis can optimize the clinical information obtained from CCTA scans and potentially avoid downstream diagnostic testing that may add unnecessary complexity, time, radiation exposure, and cost to the diagnostic workup of suspected or known CAD.[12,13]

The following table shows the various elements included in the AI-QCT service (0623T-0626T) vs. the CCTA service (75574):

Elements/Attributes	AI-QCT (0623T-0626T)	CCTA (75574)
Precise whole-heart quantification and characterization of:		
Calcified plaques	X	
Non-calcified plaques	X	
Low-density, high-risk plaques	X	
Positive remodeling index	X	
Precise percent stenoses	X	
Identification of ischemia *(when identified and performed)*	X	
Visualization and evaluation of coronary arteries and bypass grafts (when present)		X
Evaluation of cardiac structure and morphology		X
Assessment of cardiac function		X
Evaluation of venous structures		X
Evaluation of non-cardiac structures (e.g., lungs, mediastinum, pleura, pulmonary vessels, chest wall)		X
Qualitative identification of plaques		X
Visual estimation of stenoses		X

Per the language provided by the CPT Editorial Panel, and as the CCTA and AI-QCT services are not mutually exclusive procedures, we urge the Centers For Medicare & Medicaid Services

(CMS) to remove these NCCI edits. Maintaining these edits will lead to significant reductions in provider and beneficiary/patient access to this innovative technology. Since the service is performed in both non-facility and hospital settings, we request that CMS remove these edits from both the Practitioner and Hospital PTP files.

Thank you for your time and consideration of this request. You may contact Maria Tran mtran@acr.org or Dr. Kathy Krol kathykrol@aol.com with any questions.
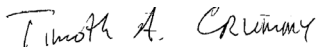
Sincerely,

Mark D. Alson, MD, FACR, RCC
ACR, Chair, Coding & Nomenclature

Randall Thompson, MD, FACC
Chair, ACC Coding Work Group

Timothy Crummy, MD, FACR, RCC, RCCIR
ACR, Co-Chair, Coding & Nomenclature
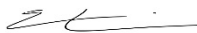ARRS, CPT Advisory Committee

Andrew J. Degnan, MD
AUR, CPT Advisor

C. Matthew Hawkins, MD, FSIR
SIR Chair, Economics Committee

Tina Young Poussaint, MD, FACR
ASNR, President 2020-2021

Eric Matthew Rubin, MD, RCC, FACR
RSNA, CPT-4 Advisory Committee

Eric Williamson, MD, MSCCT
President, Society of Cardiovascular Computed Tomography

References

1. American Medical Association, CPT 2022 Professional Edition, 2020.
2. American Medical Association, Auto Quantification and Characterization of Coronary Atherosclerotic Plaque, CPT Assistant, Vol. 31, Issue 10, Oct 2021.
3. https://www.accessdata.fda.gov/cdrh_docs/pdf19/K190868.pdf
4. https://www.accessdata.fda.gov/cdrh_docs/pdf20/K202280.pdf
5. Choi AD, Marques H, Kumar V et al. CT EvaLuation by ARtificial Intelligence For Atherosclerosis, Stenosis and Vascular MorphologY (CLARIFY): A Multi-center, international study. J Cardiovasc Comput Tomogr. 2021. Nov-Dec;15(6):470-476.J Cardiovasc Comput Tomogr. 2021 Nov-Dec;15(6):470-476.
6. Lee SE, Chang HJ, Sung JM, Pet al. Effects of Statins on Coronary Atherosclerotic Plaques: The PARADIGM Study. JACC Cardiovasc Imaging. 2018 Oct;11(10):1475-1484.
7. Budoff MJ, Bhatt DL, Kinninger A, Lakshmanan S, Muhlestein JB, Le VT, May HT, Shaikh K, Shekar C, Roy SK, Tayek J, Nelson JR. Effect of icosapent ethyl on progression of coronary atherosclerosis in patients with elevated triglycerides on statin therapy: final results of the EVAPORATE trial. Eur Heart J. 2020 Oct 21;41(40):3925-3932.
8. Chang HJ, Lin FY, Lee SE, et al. Coronary Atherosclerotic Precursors of Acute Coronary Syndromes. J Am Coll Cardiol. 2018 Jun 5;71(22):2511-2522.
9. Williams MC, Kwiecinski J, Doris M, et al. Low-Attenuation Noncalcified Plaque on Coronary Computed Tomography Angiography Predicts Myocardial Infarction: Results From the Multicenter SCOT-HEART Trial (Scottish Computed Tomography of the HEART). Circulation. 2020 May 5;141(18):1452-1462. doi: 10.1161/CIRCULATIONAHA.119.044720.
10. Ferencik M, Mayrhofer T, Bittner DO, et al. Use of High-Risk Coronary Atherosclerotic Plaque Detection for Risk Stratification of Patients With Stable Chest Pain: A Secondary Analysis of the PROMISE Randomized Clinical Trial. JAMA Cardiol. 2018 Feb 1;3(2):144-152.
11. Tomizawa N, Yamamoto K, Inoh S, Nojo T, Nakamura S. High-risk Plaque and Calcification Detected by Coronary CT Angiography to Predict Future Cardiovascular Events After Percutaneous Coronary Intervention. Acad Radiol. 2018 Apr;25(4):486-493.
12. Kim Y, Telluri A, LipkinI, Bradley A, et al, Selective Referral Using Artificial Intelligence Guided CCTA Versus Direct Referral for Individuals Referred to Invasive Coronary Angiography for Suspected Coronary Artery Disease: A CONSERVE Trial Sub-study. *In-Submission* Radiology AI 2021.
13. Lipkin I, Telluri A, KimY, et al. Performance and Utility of AI Evaluation of Coronary Stenosis on CT Coronary Angiography vs Nuclear Myocardial Perfusion Imaging for Prediction of Stenosis and Ischemia *In-Submission* Radiology CT Imag 2021.